

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/11 has been entered.

2. Claims 34-39 are all the pending claims for this application.

3. Claims 34, 35, and 38 were amended in the Response of 1/19/10.

4. Claims 34-39 are all the pending claims under examination.

### **Withdrawal of Rejections**

#### ***Claim Rejections - 35 USC § 112, first paragraph***

##### ***Written Description***

5. The rejection of Claims 34-39 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

Applicants allegations on pp. 3-7 with the emphasis being that the antibody fragments are themselves immunogenic and not required to be functional, *per se*, in their binding activity to any known antigen is found to be persuasive. "Instead, they are injected as a vaccine, and are intended to function as antigens" and "As antibody chains of an anti-EpCam antibody, they would be expected to have at least some of the

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antigenic features of the complete anti-EpCam antibody, such as antigenic linear epitopes which are found in the complete antibody. These linear epitopes would be expected to be present even when there is not complete folding of the antibody, because they depend primarily on the order of the amino acid sequence."

### ***Enablement***

6. The rejection of Claims 34-39 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for introducing any fragment of the constant region from an IgG2 antibody into the constant region of any IgG1 antibody of SEQ ID NO: 2, 3, 4 and/or 5 in order to obtain a constant region comprising any hamster or primate glycosylation and being immunogenic in any primate is withdrawn.

Applicants allegations on pp. 7-8 of the Response of 3/24/11 in addition to the 1.132 Declaration of Dr. Schuster demonstrating antigenicity in a primate for a claimed species of antibody are found to be persuasive. "Dr. Schuster points out that the antibodies of the present invention are not being used for their antibody function per se, but are instead used as antigens (Schuster Declaration, page 3). Dr. Schuster points out that both lineal' epitopes and conformational epitopes (three-dimensional epitopes) based on the "foreign" routine sequences are present in a properly folded antigen. Thus, "the presentation of these linear epitopes elicits as consequence a humoral and cellular immune response" (Schuster Declaration, page 3)."

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***Conclusion***

7. Claims 34-39 are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNN BRISTOL whose telephone number is (571)272-6883. The examiner can normally be reached on M, Tue, Thur, Fr from 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/  
Primary Examiner, Art Unit 1643